K020785

AUG 2 8 2002

7.0 510(k) Summary

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2579

Contact: Amy S. Krall, RA Specialist

DEVICE NAME: Introcan® Safety™ IV Catheter

COMMON OR USUAL NAME: Safety Intravascular Catheter

DEVICE CLASSIFICATION: Class II, 21 CFR 880.5200: Intravascular Catheter and 880.5440: Intravascular Administration Set

PREDICATE DEVICE:

B. Braun Medical Inc.
Introcan Safety IV Catheter, K982805.
Johnson and Johnson
JELCO™, JELCO-W™ and JELCO Plus I™, K990236
Becton Dickinson
INSYTE®, INSYTE-W® and INSYTE ® AUTOGUARD II catheters, K971339

DESCRIPTION: B. Braun Medical's Introcan Safety IV Catheter is a passive needle stick prevention device used for arterial and venous access for the infusion of fluids, drugs and/or blood components. 14 - 22 gauge catheters may be used with power injectors for which the maximum pressure setting is 300 psi.

The Introcan Safety IV Catheter is available in 14 - 24 gauge sizes, and both winged and non-winged versions.

INTENDED USE: Passive anti-needle stick device for venous or arterial access for the infusion of fluids, drugs, and/or blood components. 14 - 22 gauge catheters may be used with power injectors for which the maximum pressure setting is 300 psi.

SUBSTANTIAL EQUIVALENCE: The Introcan Safety IV Catheter is identical in materials and design to B. Braun Medical's premarket notification, Introcan Safety IV Catheter, K982805. The Introcan Safety

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IV Catheter is similar in indications for use to Johnson and Johnson Jelco™ catheters, K990236 and Becton Dickinson INSYTE® catheters, K971339. Functional testing was performed to support that there are no new issues of safety or effectiveness raised by the expanded indications for use for the Introcan® Safety™ IV Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2002

Ms. Amy S. Krall
Regulatory Affairs Specialist
B. Braun Medical, Incorporated
824 Twelfth Avenue
Bethlehem, Pennsylvania 18018

Re: K020785
Trade/Device Name: Introcan Safety™ IV Catheter
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: June 18, 2002
Received: June 19, 2002

Dear Ms. Krall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K020785

Device Name: Introcan® Safety™ IV Catheter

Indications For Use:
Passive anti-needle stick devices for venous or arterial access for the infusion of fluids, drugs, and/or blood components. 14 - 22 gauge catheters may be used with power injectors for which the maximum pressure setting is 300 psi.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Patricia Cucento
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K020785